IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327 MDL No. 2327** **JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **Wave 2**	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE DR. SUZANNE PARISIAN, M.D.

Plaintiffs respectfully submit this Memorandum of Law in Opposition to Defendants Ethicon, Inc. and Johnson & Johnson's ("Defendants") Motion to Exclude Dr. Suzanne Parisian, M.D.

Introduction and Qualifications of Dr. Suzanne Parisian

Dr. Parisian is medical doctor, pathologist, and regulatory expert who has served as regulatory and medical device consultant since 1995. *See*, Def. Ex. B at pp. 5-8. Dr. Parisian was an FDA employee for over four years, and dealt with both pre-market and post-market issues relating to medical devices - the precise issues about which she intends to testify in these cases. *Id.* During her tenure at FDA, Dr. Parisian was the primary clinician tasked with making over 260 health risk assessments regarding medical devices. *Id.* at pp. 5-6. After working at FDA, Dr. Parisian founded a medical device consulting firm where she instructs medical device manufacturers regarding FDA regulatory requirements, including 510(k) submissions and product labeling requirements. *Id.* at pp. 6-7. Both in her position as an FDA employee and in

her consulting business, Dr. Parisian reviewed hundreds of marketing applications and draft labeling for a conglomeration of medical devices. *Id* at p. 8. Additionally, she has been involved with product design and submissions for approval or clearance to the FDA. She has even written a book on FDA regulatory issues. *Id.* at p. 7. In total, Dr. Parisian is eminently qualified to render her opinions because she has decades of experience dealing with medical device regulatory issues in a professional capacity.

Legal Standard

The task of evaluating the reliability of expert testimony is uniquely entrusted to the district court. *Daubert v. Merrell Dow Pharmaceuticals, Inc*. 509 U.S. 579, 589 (1993). District courts enjoy "considerable leeway" in determining the admissibility of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Under Federal Rule of Evidence ("Rule") 702 if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," (3) which have been reliably applied "to the facts of the case." See *Tyree*, 2014 WL 5320566 at *2; see also *In re C.R. Bard, Inc*., 948 F. Supp. 2d 589, 601 (S.D.W.Va. 2013). A two part test governs the admissibility of expert testimony (and is combined with Rule 702's qualification standard). See Rule 702; see also Tyree, 2014 WL 5320566 at *2. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597; see also *Tyree*, 2014 WL 5320566 at *2.

The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence from which the court can determine that the

proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998); *Tyree*, 2014 WL 5320566 at *2. All Daubert demands is that the trial judge serve as a gate keeper and make a "preliminary assessment" of whether the proffered testimony is both reliable and helpful. *Tyree*, 2014 WL 5320566 at *3. In making the required preliminary assessment, the trial court "'need not determine that the proffered expert testimony is irrefutable or certainly correct'" because, as with all testimony, it will be subject to "testing" by cross-examination, contrary evidence, and instruction on the burden of proof. See *Id*. (quoting *U.S. v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006)).

Legal Standard as Applied to Dr. Parisian

The testimony Dr. Parisian seeks to proffer is in full compliance with the standards set forth in Rule 702, Daubert and its progeny. See Rule 702; see also *Daubert*, 509 U.S. at 597 (to be admitted evidence must "rest [ ] on a reliable foundation and [be] relevant"); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) ("[T]he obligation of a district court to determine whether expert testimony is reliable and relevant applies to all expert testimony [i.e. scientific and non-scientific]."). In addition, Plaintiffs aver that applicable law requires that Rule 702 be applied flexibly, see *Daubert*, 509 U.S. at 594, so as to uphold the general framework of the Rules which favors the admissibility of evidence over non-admissibility. *Id*. at 588; see also *Tyree*, 2014 WL 5320566 at *3. In short, "the rejection of expert testimony is the exception rather than the rule." *U.S. v. Stanley*, No. 12-4572, 2013 WL 3770713 at *1 (4th Cir. July 19, 2013) (internal quotations omitted in the cited quotation.). As such, Plaintiffs respectfully submit that the expert testimony proffered by Dr. Parisian should be admitted as set forth herein and that Ethicon's Motion should be denied.

Argument

Rather than addressing the substance of Dr. Parisian's opinions, Ethicon attempts to obfuscate the Court's inquiry by presenting to the Court a hap hazard conglomeration of cases where Dr. Parisian's opinions were limited, often only in part, to support sweeping and generalized arguments to exclude Dr. Parisian's opinions. These opinions, involving different cases and different facts, have minimal relevance to the Court's inquiry *in this case*. In fact, Defendants conveniently fail to mention that Dr. Parisian has been allowed to testify in TVM state courts actions, and, in fact, proffered testimony in at least one TVM trial, *Barba v. Boston Scientific*. *See* Trial Trans. (5/18/2015) at 21:4-23:12; 26:11-98:17, attached as Ex. A, *Barba v. Boston Scientific*, C.A. No. N11c-08-050 (Del. Sup. Ct.). In *Barba*, the Court found Dr. Parisian's opinions relevant and reliable, and allowed her to testify concerning the FDA regulatory processes, the 510(k) clearance process, Boston Scientific's actions within that process, and Boston Scientific's transvaginal mesh device labeling. *Id*.

Here, Defendants argue against opinions that Dr. Parisian does not offer, including opinions that Dr. Parisian overtly states she *will not* offer, in an attempt to conclude that Dr. Parisian has exceeded the bounds of her expertise. Defendants acknowledge that Dr. Parisian, both in her reports and depositions, specifically states that she will not testify as to causation, medical standards of care, or design defects. *See*, Def. Memo at 4-6. Yet, in their memo Defendants quote seven opinions from Dr. Parisian's report that supposedly overstep these boundaries. *Id*. at 5-6. Notably, the opinions cited by Defendants are not opinions related to causation, the medical standard of care, or manufacturing defects. Rather, the opinions cited by Defendants are regulatory opinions, which is Dr. Parisian's specific area of expertise. Not only does Defendants' strategy create arguments that do not exist, but this strategy is blatantly flawed

and should be summarily rejected by the Court. Defendants fail to confront the reality of Dr. Parisian's report; that the only relevant inquiry before this Court is the reliability and relevance of Dr. Parisian's opinions on the TVT-S, not the illusory opinions that Dr. Parisian does not offer or seek to present at trial.

I. Dr. Parisian Is Qualified To Offer The Opinions Set Forth In Her Report.

Defendants' motion is a classic straw man argument. Defendants' arguments center around their position that Dr. Parisian is unqualified to offer her opinions because "Dr. Parisian does not have sufficient qualifications to present this testimony, nor does she employ any methodology---let alone a reliable one. Although she is a licensed medical doctor and pathologist, **she has not treated a patient for nearly 30 years**." Def. Mot. at 6. First, the fact that she has not recently treated patients is wholly irrelevant with respect to her qualifications, methodology, and opinions that she offers in these cases. When this Court was faced with similar criticisms of another regulatory expert by the Defendants in this MDL, this Court held that:

> While it is true that Dr. Pence is not a doctor or biomedical engineer, she has more than forty years of experience in the research and development of pharmaceuticals and medical devices" and that when considering her additional role in presiding over a company that "**provides 'advice, guidance, and product development services to . . . medical device companies in the areas of strategic planning, preclinical testing, clinical trials design and conduct . . .' that "this experience is relevant to her opinion that Ethicon failed to act as a reasonably prudent manufacturer in testing the TVT, and she is therefore qualified to testify by her 'knowledge, skill, experience, training, or education**[.] Fed. R. Evid. 702.

In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig., 2014 WL 186872, *30.

This Court has already considered, and rejected, the argument that specific, clinical expertise using a pelvic mesh device or practicing gynecology is an absolute prerequisite to offering an opinion on the labeling of such a device. *Id* at *29-32; *In re C.R. Bard, Inc.*,

948 F. Supp. 2d, at 627-631. Instead, such evidence should go to the weight of the expert's opinions at trial. Similar to other regulatory experts who have testified in mesh cases; Dr. Parisian has over twenty (20) years of experience in the drug and device regulatory field and over twenty-four (24) years of experience in the research and development of medical devices. Def. Ex. B at p. 6. She also worked at FDA, conducting both pre-market and post-market analyses of hundreds of medical devices. *Id.* Just as doctors Kessler and Pence were deemed qualified to offer expert regulatory opinions on the basis of their work for the FDA in this MDL, as well as the Bard and BSC MDLs, Dr. Parisian is qualified based on her similar experience, and her opinions are admissible here.

Despite Dr. Parisian's clear qualifications to offer her opinions as a regulatory expert, Defendants attempt to recast the nature and foundation of her opinions. For example, Defendants highlight selected excerpts of Dr. Parisian's opinions to give the illusion that her opinions exceed her expertise. Def. Mtn. at 5-6. However, each of the specific opinions highlighted by Defendants are regulatory opinions. This Court has previously held that these types of regulatory opinions, such as the appropriateness of premarket testing and the contents of a medical device 510(k) application are admissible where a regulatory expert relies on studies and international standards. *See Mathison v. Boston Sci. Corp*., No. 2:13-CV-05851, 2015 WL 2124991, at *15 (S.D.W. Va. May 6, 2015); *Sanchez v. Boston Sci. Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *34 (S.D.W. Va. Sept. 29, 2014), reconsideration denied, No. 2:12-CV-05762, 2014 WL 5320559 (S.D.W. Va. Oct. 17, 2014). Here, Dr. Parisian incorporates a multitude of international standards, including GHTF standards, NICE recommendations, and the HAS standards. Def. Ex. B at pp. 9, 83. Accordingly, the Court should not stray from its previous rulings and should deny Defendants' motion to exclude Dr. Parisian.

II. Defendants' Intent, Motive and "Narrative" Arguments Lack Merit.

Ethicon seeks to exclude Dr. Parisian's testimony, to the extent that it constitutes a narrative of documents or an expression of corporate intent. Def. Mtn. at 10-14. Plaintiffs will comply with this Court's prior rulings and will not elicit testimony from Dr. Parisian on Defendants' state of mind, motives, or intent. However, much of the testimony Defendants label as "state of mind" is merely a description of Ethicon's code of conduct, relevant industry standards, and Dr. Parisian's opinion that Ethicon failed to comply with these standards. These opinions do not necessarily delve into "state of mind" testimony that the Court has previously precluded, and are instead helpful to the jury by informing as to relevant industry and regulatory standards. Whether Ethicon failed to comply with its code of conduct or industry standards is not, as Ethicon asserts, knowledge or state of mind testimony but rather opinions as to industry standards which are in turn helpful to the jury. Similarly, whether, how, and when Ethicon communicated safety information to physicians and patients goes to the heart of Plaintiffs' failure to warn claims.

The opinions offered, are thus both relevant and helpful, as Dr. Parisian's expertise on regulatory and industry standards aids the jury in determining whether Defendants breached their code of conduct. Moreover, this Court rejected a similar argument that Ethicon advanced in *Lewis* with respect to "narrative" testimony. 2014 WL 186872, at *21. In *Lewis*, Ethicon argued that Dr. Bruce Rosenzweig's testimony was inadmissible because "much of Dr. Rosenzweig's expert report is a summary of company documents, exhibits, and websites." *Id.* This Court rejected that argument, ruling that reliance on those materials "is helpful to the jury [in] understand[ing] the plaintiffs' . . . claims." Similarly, in *Cisson v. C.R. Bard, Inc.*, this Court allowed an expert to offer factual narrative testimony "to the extent that [the narratives] may

present the bases for the expert opinions." 948 F. Supp. 2d 589, 646 (S.D.W. Va. 2013). Likewise, the Court in *Smith v. Pfizer* rejected this exact argument, holding "[Plaintiff's expert] may properly testify as to his interpretation of internal marketing-related documents that he relied on in forming his opinions." 714 F. Supp. 2d 845, 857 (M.D. Tenn. 2010). The same result is warranted here. For these reasons, the Court should deny Defendants' motion.

Dr. Parisian's proffered testimony is not an impermissible narrative, but rather proper testimony for the jury that is precisely within her realm of expertise. Other courts have determined that an expert may properly testify about, or comment upon, any document or exhibits in evidence, and may explain "the regulatory context in which they were created, defining any complex or specialized terminology or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge." *In re Fosamax*, 645 F.Supp.2d at 192. Thus, the factual materials considered by Dr. Parisian are not intended to be the subject of her testimony in and of themselves. Rather, the documents, evidence and factual matters referenced form the basis of her opinion and are relevant and helpful to the jury in explaining the regulatory context in which they were created. This testimony illustrates the considerations that are relevant at different stages of the regulatory process, and allows Dr. Parisian to apply her expertise to draw inferences that would not otherwise be apparent to the jury. The use of factual materials in this way does not to violate the rule against factual narratives. *Id.*

Further, Plaintiffs disagree with the characterization of Dr. Parisian's testimony as a factual narrative because the "appropriate solution" is not to "parse the expert's report;" but, rather, to trust that plaintiffs' counsel will only present the facts necessary to the expert's opinion and that the Court will be able to cut off lengthy factual narratives (if any) at trial.

In re C.R. Bard, Inc., 948 F. Supp. 2d, at 645-646. Thus, if Defendants truly believe that there is a lack of connection between the facts and Dr. Parisian's expert opinions, the better time to object to narrative testimony is at trial. *Staub v. Breg, Inc.*, 2012 WL 1078335 *3 (D. Ariz. 2012).

III. Dr. Parisian's Opinion That Ethicon Failed To Comply With Applicable Post Market Vigilance Standards Is Admissible.

Medical device manufacturers have an obligation to ensure that their labeling is and remains adequate over the course of the lifecycle of its products. This is the heart of a failure to warn claim. As the product was introduced and remained on the market, a central question is whether Ethicon's Instructions for Use ("IFU") adequately informed physicians of known or knowable safety risks so both surgeons and patients could make informed decisions. Federal Regulations require medical device companies to report and analyze safety information as it is received while a product remains on the market. *See e.g.*, 21 C.F.R. § 803.50(a). For the reasons more fully stated below, Defendants' arguments confuse the nature and scope of the opinions offered by Dr. Parisian with respect to adverse event reporting or other data regarding the safety profile of the TVT-S device, and should therefore be denied.

For example, Defendants' argument to exclude Dr. Parisian's opinions on post-market vigilance is misplaced. Ethicon attempts to characterize this testimony as strictly whether, how, and when Ethicon communicated safety information to the FDA. Such testimony is admittedly irrelevant and will not be offered at trial. However, whether, how and when Ethicon communicated safety information to physicians and patients goes to the heart of Plaintiffs' failure to warn claims and is therefore admissible.

IV. Dr. Parisian Is Qualified To Opine Upon Foreign Regulatory Matters And This Testimony Will Be Helpful To The Jury.

Ethicon argues that Dr. Parisian is not qualified to opine on foreign regulatory matters because she has only a "'working familiarity' with 'international standards and requirements'". Def. Mot. at 14. However, Dr. Parisian explains in detail her unique qualifications to opine on foreign regulatory matters, including practical application of global industry standards. Def. Ex. B at p. 11, ¶ 18. These experiences include presentations to foreign medical associations as well as, "helping regulated industry obtain acceptance and reimbursement by foreign regulatory agencies." *Id*. Not only, does Dr. Parisian have practical working experience in this field, but she provides a detailed explanation of her methodology on this point. *Id*. Although she may not be qualified to opine on the "laws" of foreign counties, her report and testimony indicate that her opinions do not delve into such matters, but are instead limited to global *regulatory standards*, to which she is qualified. Dr. Parisian's considerable experience renders her qualified to offer these opinions.

Dr. Parisian's opinions on international regulatory standards are similarly helpful to the jury. This court has previously held that opinions on such standards are admissible. *See Mathison v. Boston Sci. Corp*., No. 2:13-CV-05851, 2015 WL 2124991, at *15 (S.D.W. Va. May 6, 2015) ("GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of the GHTF that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA.") (internal citations omitted). Further, the Court found that such reliance on international standards was both reliable and helpful to the jury where a regulatory expert opined on such matters as premarket testing and some product labeling matters. *Id* at *15. Because Dr. Parisian's reliance on international standards is both reliable and helpful, her

opinions should not be excluded *per se* simply because she incorporates international standards within her methodology.

V. Dr. Parisian Is Qualified To Opine On TVT-S Warnings.

Next Defendants attack Dr. Parisian's qualifications to testify and opine about warnings, first arguing that other Courts have excluded her testimony in unrelated cases and secondly that Dr. Parisian lacks the experience and qualifications to form her opinions. Defendants' first argument is meritless and the second argument incorrect. *See e.g., Keffer v. Wyeth*, 791 F. Supp. 2d 539, 545 (S.D.W. Va. 2011) (denying summary judgment on the basis of Dr. Parisian's testimony as to warnings). Defendants' criticism of Dr. Parisian's qualifications centers almost exclusively on her lack of involvement with the specific devices at issue, either drafting patient brochures or IFUs for the devices at issue, or treating patients. Def. Mot. at 16. These objections are unavailing as this Court has previously held that treatment of patients is not a prerequisite for *Daubert* admissibility. *See In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2014 WL 186872, *30. Here, although Dr. Parisian has not drafted an IFU for the TVT-S, Ethicon's assertion that Dr. Parisian "has never drafted an IFU or patient brochure" is patently false as her testimony demonstrates:

> Q. Did you help create an IFU?
>
> A. For the investigators, yes, sir.

Def. Ex. E at 54:2-3, *see also*, Def. Mtn. at 17.

Similarly, Dr. Parisian has experience with patient brochures:

> Q. Have you ever drafted a patient brochure for a surgically implantable device?
>
> A. At the FDA I commented on them in terms of surgically implantable devices. I have not drafted it from square one. But in terms of medical devices, you're often more interactive with companies in terms of – like, I know I was involved with implantable cardiac defibrillators when

> they first came out and also some of the – so those would have been issues that I was looking at the labels, but I didn't draft them.

Id. at 56:5-15.

Thus, Defendants' argument is predicated on the assumption that an expert must have been directly involved in drafting IFU's or patient brochures for the *exact device* at issue in order to pass *Daubert*. Such an assumption has no support in the law and this Court has previously found regulatory experts qualified to render similar testimony in the absence of direct involvement with product specific IFUs and patient brochures. *See Winebarger* 2015 WL 1887222, at *18 (finding regulatory expert qualified to testify on opinions offered in expert report which included IFUs and patient brochures).[1] Rather, the fact that she has not drafted on IFU for these specific devices goes towards the weight of her testimony at trial, not it's admissibility. Further, as set forth above, Dr. Parisian testified in the *Barba* trial with respect to Boston Scientific's IFU's, even though she had never crafted an IFU for the two devices at issue in that case. Ex. A, Trial Trans. (5/18/2015) at 21:4-23:12; 26:11-98:17. Dr. Parisian's extensive experience drafting or commenting upon IFU's and patient brochures renders her sufficiently qualified to testify as to her opinions.

Similarly, Dr. Parisian's failure to speak with physicians who implanted the TVT-S is insufficient to show that she is unqualified to testify on the issue of warnings and labels. Ethicon argues that failing to speak with physicians or surgeon renders her unqualified to opine on warnings, however such a shortcoming is not grounds for exclusion. Def. Mot. at 17. This Court has previously held that "[a]n expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert,* so long as the expert has other 'sufficient facts or data' to

[1] The Court did exclude some of Dr. Pence's opinions as unreliable, however no opinions were excluded on the basis of qualification. *Winebarger*, 2015 WL 1887222, at *20.

support her opinion. Fed.R.Evid. 702; *Mathison v. Boston Sci. Corp*., No. 2:13-CV-05851, 2015 WL 2124991, at *18 (S.D.W. Va. May 6, 2015). Here, Dr. Parisian's opinions are predicated on sufficient facts and data to render her opinions reliable and the criticisms offered by Ethicon are better reserved for cross examination at trial. *Id*.

VI. Dr. Parisian Employs a Reliable Methodology to Form Her Opinions On TVT-S Warnings.

Defendants' criticism of Dr. Parisian's methodology centers upon a perceived lack of utilization of any specific methodology or industry standards to form her warnings opinions. Def. Mtn. at 18. Defendants argue that, because Dr. Parisian admits that "FDA never found the material in the IFU to be deficient and never proposed label changes for the TVT-Secur," " Dr. Parisian did not conduct a readability study of the TVT-Secur IFU," Dr. Parisian, "did not conduct a survey of surgeons to determine what information the surgeons gleaned from the IFU," "she has never spoken with a medical doctor about her criticisms of the IFU," and "she has never conducted any surveys or studies of patients as to their understanding of the TVT-Secur patient brochure," that Dr. Parisian's warnings opinion are the product of faulty methodology. Def. Mtn. at 18. This argument is a red herring. Dr. Parisian forms her opinions on the adequacy of the TVT-Secur warnings through employment of global industry standards and review of FDA and Ethicon documents. Def. Ex. B at pp. 9-11, ¶s 14-17. A cursory review of Dr. Parisian's opinion that the TVT-Secur was marketed with inaccurate and misleading labeling reveals that Dr. Parisian arrived at this conclusion by examining what the FDA requested of Ethicon, Ethicon's actions, and the data available to Ethicon that informed its actions. Def. Ex. B at p. pp. 86-100. This opinion, and other similar opinions offered by Dr. Parisian, do not require specialized knowledge of surgical procedures, knowledge of the risks of non-mesh procedures or complications, all factors Defendants consider relevant in arguing that Dr. Parisian fails to

employ a reliable methodology. Instead, Dr. Parisian's opinions revolve around regulatory expertise and industry standards. Because Dr. Parisian's opinion here centers upon the accuracy of the product label, Defendants' arguments related to adequacy of the methodology are misplaced and irrelevant.

CONCLUSION

For the above reasons, Dr. Parisian is qualified to render the opinions she is called to make and those opinions are relevant and based on reliable methodology and will assist the jury. Consequently, her opinions are admissible and Defendants' Motion should be denied in full.

Dated: August 8, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to CM/ECF participants registered to receive service in this case.

/s/ Jeffrey M. Kuntz
Counsel for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2016, a true and correct copy of this Response, and exhibits, was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.